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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KALLIS, RUSSELL

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 03/26/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/669,476

Applicant(s)

BOTELLA, JOSE RAMON

Examiner

Russell Kallis

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-59 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 34-59 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Sequence Rules

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is still not in sequence compliance. Applicant must amend the application to identify all sequences by their SEQ ID NO:.

All of the sequences in the specification must have a sequence identifier, e.g. sequences on page 9/1, Table 1, and all of the Figures (or at least the Brief Description of the Drawings on p. 12).

All of the sequences in the sequence listing must be identified in the specification.

Full compliance with the Sequence Rules is required in response to this Official action. A complete response to this Official action should include both compliance with the Sequence Rules and a response to the issues set forth below. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

Priority

2. The claim to priority in the amendment filed 9/25/00 is improper. Applicant must recite the filing date of prior U.S. applications. Also the type of priority between the prior U.S. application and the PCT application must be stated. The claim to priority should be canceled and replaced with the following:

This application is a continuation of U.S. Application Serial No. 09/043,687 filed 3/20/98, now U.S. Patent 6,124,525, which is a 371 of PCT/AU96/00591, filed 6/10/97.

Specification

3. A substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a) because the pages of the specification are numbered improperly, i.e. pages 9/1, 9/2, etc. are improper. The examiner respectfully asks Applicant to send in a substitute specification with proper consecutive page numbers.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

Claim Objections

4. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 34-46 in the amendment filed 2/11/02 have been renumbered as claims 47-59.

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Claims 47-59 in the amendment filed 2/11/02 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 34-46. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 54-57 and 59 are rejected under 35 U.S.C. 112, second paragraph, because they depend from cancelled claims.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 34-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a nucleotide sequence of sufficient length to regulate the level of ACC synthase gene expression and methods of producing a transgenic papaya or mango plant with inhibited fruit senescence comprising transformation of mango or papaya with antisense or

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sense ACC synthase cDNA of sufficient length to reduce the level of ACC synthase gene expression.

Applicant teaches isolation via reverse transcription, and amplification of RNA, from pineapple, papaya, and mango fruit, of pineapple, papaya, and mango ACC synthase cDNA; SEQ ID NO: 1, 3, 5, 7, 9; encode SEQ ID NO: 2, 4, 6, 8, 10 (Examples 1-3). Applicant teaches microprojectile bombardment of papaya somatic embryogenic tissue with antisense papaya ACC synthase genes (SEQ ID NO: 3 and 5), recovery, selection, and regeneration of putatively transformed shoots (Example 4). Applicant teaches *Agrobacterium* mediated transformation of mango explants with antisense mango ACC synthase genes (SEQ ID NO: 7 and 9) and recovery and selection of putatively transformed tissue on selection media (Example 5).

Applicant does not teach a transgenic papaya or mango plant with inhibited fruit senescence by means of transformation with antisense ACC synthase cDNA. Applicant does not teach fragments of an antisense ACC synthase cDNA fragment that are of sufficient length to inhibit fruit senescence.

The unpredictability in phenotype in transgenic plants expressing antisense cDNA fragments was shown in Genetic Manipulation of Condensed Tannins in Higher Plants by Robbins *et al.* Plant Physiol.(1998) 116: 1133-1144. The authors found it noteworthy that the three constructs used in the experiment were from different sections of one cDNA. The results showed tissue specific reduction and increases of cDNA expression that varied with both construct and insertion event. Another example shows a 3' half of an antisense cDNA construct was more effective than the 5' half in Inhibition of flower pigmentation by antisense CHS genes: promoter and minimal sequence requirements for the antisense effect by van der Krol *et al.*,

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Plant Molecular Biology 14: 457-466, 1990. Another consideration in antisense fragments having an unpredictable effect is when the fragment is small enough to comprise a relatively length of a conserved motif or region of a gene such that it would exert an antisense effect upon other expressed genes in the genome that have the same motif or region.

In view of the lack of guidance provided in the specification, one of skill in the art would be required to screen a multitude of sequences of various lengths and from different regions of SEQ ID NO: 1, 5, 7, and 9, or a sequence that hybridizes thereto, to identify those that successfully inhibit only ACC synthase in transgenic plants and suppress fruit senescence. Therefore, undue experimentation would be required.

Given the lack of guidance and the lack of working examples in the specification, the breadth of the claims, with respect to the use of the phrase "of sufficient length to regulate ACC synthase gene expression", and the unpredictability in the art, undue trial and error would be needed to practice the invention as claimed. Therefore the invention is not enabled.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 34-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,124,525. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed towards nucleotide sequences that hybridize to SEQ ID NO: 1, 5, 7, or 9, the transformation vector, comprising said nucleotide sequences, methods of transforming mango and papaya, and transgenic mango and papaya plants thereby produced.

11. All claims are rejected.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Kim Davis, whose telephone number is (703) 308-0009.



Russell Kallis Ph.D.
March 23, 2002

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
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